

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rule making related to cytomegalovirus testing

The Department of Public Health hereby amends Chapter 3, “Early Hearing Detection and Intervention (EHDI) Program,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 135.131 and 2017 Iowa Acts, Senate File 51.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 135.131 and 2017 Iowa Acts, Senate File 51.

Purpose and Summary

Infants born to mothers infected with cytomegalovirus (CMV) during pregnancy may develop a congenital cytomegalovirus (cCMV) infection, which may lead to hearing loss or other serious complications. These amendments add definitions for “congenital cytomegalovirus” and “cytomegalovirus,” add testing for CMV to the rule that outlines the procedure to accommodate parental objection, add a new rule 641—3.11(135) as described below, and outline the procedure for documentation of parental refusal of newborn testing for CMV.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on December 20, 2017, as **ARC 3519C**. No public comments were received. Since publication of the Notice, a new Item 4 has been added to adopt rule 641—3.11(135), which more clearly states the intent of 2017 Iowa Acts, Senate File 51, regarding when testing for cCMV should occur, information that shall be provided to parents, and the procedures for parental objection. A new Item 3 has also been added to renumber existing rule 641—3.11(135) as 641—3.12(135), and the original Item 3 has been renumbered as Item 5 herein.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on March 14, 2018.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department’s variance and waiver provisions contained in 641—Chapter 178.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on May 16, 2018.

The following rule-making actions are adopted:

ITEM 1. Adopt the following new definitions of “Congenital cytomegalovirus” and “Cytomegalovirus” in rule **641—3.1(135)**:

“*Congenital cytomegalovirus*” or “*cCMV*” means an infection where cytomegalovirus is transmitted to the fetus in the prenatal period.

“*Cytomegalovirus*” or “*CMV*” means a kind of herpes virus that usually produces very mild symptoms in an infected person but may cause severe neurological damage in a person with a weakened immune system and in a newborn.

ITEM 2. Amend rule 641—3.2(135) as follows:

641—3.2(135) Purpose. The overall purpose of this chapter is to establish administrative rules in accordance with Iowa Code section 135.131 relative to the following:

1. Universal hearing screening of all newborns and infants in Iowa.
2. Facilitating the transfer of data to the department to enhance the capacity of agencies and practitioners to provide services to children and their families.
3. Establishing procedures for infants who were not screened or do not pass their initial hearing screening to receive appropriate follow-up to determine if the infants have normal hearing or have hearing loss.
4. Establishing the procedure for distribution of funds to support the purchase of hearing aids and audiologic services for children.
5. Establishing the procedure for documentation of parent refusal of newborn testing for congenital cytomegalovirus.

ITEM 3. Renumber rule **641—3.11(135)** as **641—3.12(135)**.

ITEM 4. Adopt the following new rule 641—3.11(135):

641—3.11(135) Congenital cytomegalovirus (cCMV) testing for newborns who do not pass the initial newborn hearing screening. If the newborn hearing screen indicates potential hearing loss, as evidenced when a newborn does not pass the initial newborn hearing screening, the birthing hospital, birth center, physician, or other health care professional required to ensure that the hearing screening is performed shall do the following:

3.11(1) Test the newborn or ensure that the newborn is tested for cCMV before the newborn is 21 days of age.

3.11(2) Provide information to the parent of the newborn regarding the birth defects caused by cCMV and early intervention and treatment resources and services available for children diagnosed with cCMV.

3.11(3) If a parent objects to the testing, follow the procedures in 641—3.13(135).

This rule is intended to implement Iowa Code sections 135.131(9) “a” and 136A.5B.

ITEM 5. Amend rule 641—3.13(135) as follows:

641—3.13(135) Procedure to accommodate parental objection. These rules shall not apply if the parent objects to the hearing screening, diagnostic audiologic assessment, or cCMV testing.

3.13(1) If a parent objects to the screening, the birthing hospital, birth center, physician, or other health care professional shall obtain a written refusal from the parent or guardian on the department newborn hearing screening or diagnostic audiologic assessment refusal form and shall maintain the original copy of the written refusal in the newborn's, infant's or child's medical record.

3.13(2) The birthing hospital, birth center, physician, or other health care professional shall send a copy of the written newborn hearing screening or diagnostic audiologic assessment refusal form to the department within six days of the birth of the newborn.

3.13(3) If a parent objects to a hearing rescreen or diagnostic audiologic assessment orally to a department EHDI staff member during follow-up, the staff member shall document the refusal in the department's designated reporting system and mail to the parent or guardian the department newborn hearing screening or diagnostic audiologic assessment refusal form in an attempt to obtain a written refusal to be maintained in the newborn's, infant's or child's medical record.

3.13(4) If a parent objects to cCMV testing, the birthing hospital, birth center, physician, or other health care professional required to ensure cCMV testing shall obtain, on the department cCMV testing refusal form, a written refusal from the parent or guardian, shall maintain the original copy of the written refusal in the child's medical record, and shall send a copy of the written refusal to the department within 21 days of the child's birth.

[Filed 3/14/18, effective 5/16/18]

[Published 4/11/18]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 4/11/18.